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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,317	07/06/2006	Birgit Bollbuck	PA/4-33165A	2729

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EXAMINER	
RAO, DEEPAK R	

ART UNIT	PAPER NUMBER
1624	

MAIL DATE	DELIVERY MODE
07/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Supplemental Notice of Allowability	Application No.	Applicant(s)	
	10/552,317	BOLLBUCK ET AL.	
	Examiner	Art Unit	
	Deepak Rao	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the amendment filed on March 24, 2009*.

2. ☒ The allowed claim(s) is/are *3,8,12 and 14-16*.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☒ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Deepak Rao/
Primary Examiner
Art Unit 1624

EXAMINER'S AMENDMENT

Note: There was an inadvertent typographical error in the Appendix attached to the previous examiner's amendment mailed on June 19, 2009. Specifically, the appendix shows that Claim 16 is dependent on claim 3, which is incorrect. Claim 16 actually is dependent on claim 12 (see page 24 of the response filed on March 24, 2009). Corrected Appendix is attached herewith.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Richard Elder on June 17, 2009.

The application has been amended as follows:

In the Specification:

On page 1, enter the following as the first paragraph below the title of the invention:

-- This application is a 371 of PCT/EP04/03819 filed April 8, 2004. --

In the Claims:

In claim 8, lines 3-5, delete the phrase: "for the treatment of an inflammatory condition comprising an autoimmune component,".

In claim 14, lines 2-3, delete the phrase:

"that are inflammatory conditions comprising an autoimmune component"

and in place insert:

-- selected from rheumatoid arthritis, arthritis chronica progrediente, arthritis deformans, hemolytic anaemia, aplastic anaemia, pure red cell anaemia, idiopathic thrombocytopenia, systemic lupus erythematosus, polychondritis, scleroderma, Wegener granulomatosis, dermatomyositis, chronic active hepatitis, myasthenia gravis, psoriasis, Steven-Johnson syndrome, idiopathic sprue, ulcerative colitis, Crohn's disease, endocrine ophthalmopathy, Graves disease, sarcoidosis, multiple sclerosis, primary biliary cirrhosis, diabetes mellitus type I, uveitis, keratoconjuctivitis sicca, vernal keratoconjunctivitis, interstitial lung fibrosis, psoriatic arthritis, glomerulonephritis, asthma, bronchitis, pneumoconiosis, pulmonary emphysema, septic shock, meningitis, pneumonia, severe burns, and AIDS-related chachexia --.

In claim 15, lines 3-5, delete the phrase: "for the treatment of an inflammatory condition comprising an autoimmune component,".

In claim 16, lines 1-2, delete the phrase:

"that are inflammatory conditions comprising an autoimmune component"

and in place insert:

-- selected from rheumatoid arthritis, arthritis chronica progrediente, arthritis deformans, hemolytic anaemia, aplastic anaemia, pure red cell anaemia, idiopathic thrombocytopenia, systemic lupus erythematosus, polychondritis, scleroderma, Wegener granulomatosis, dermatomyositis, chronic active hepatitis, myasthenia gravis, psoriasis, Steven-Johnson syndrome, idiopathic sprue, ulcerative colitis, Crohn's disease, endocrine ophthalmopathy, Graves disease, sarcoidosis, multiple sclerosis, primary biliary cirrhosis, diabetes mellitus type I,

uveitis, keratoconjuctivitis sicca, vernal keratoconjunctivitis, interstitial lung fibrosis, psoriatic arthritis, glomerulonephritis, asthma, bronchitis, pneumoconiosis, pulmonary emphysema, septic shock, meningitis, pneumonia, severe burns, and AIDS-related chachexia --.

(Copy of claims 8 and 14-16 as amended are enclosed in Appendix)

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

The reference of record, do not teach or fairly suggest the instantly claimed (pyrimidin-2-yl)-(2,2,6,6-tetramethyl-piperidin-4-yl)-amine or (pyrimidin-2-yl)-(2,6-dimethyl-piperidin-4-yl)-amine compounds. The specification disclosed the compounds to be useful as inhibitors of IKK and TNFα and due to this activity, useful in the treatment of autoimmune diseases and inflammatory conditions, see pages 200-202 of the specification. As the compounds were found to be allowable, the corresponding therapeutic use of the compounds in the treatment of specific diseases disclosed in page 202 of the specification was deemed allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Monday-Friday from 8:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Deepak Rao/
Primary Examiner
Art Unit 1624

July 13, 2009

APPENDIX

Copy of claims 8, 14, 15 and 16 as amended by examiner's amendment:

8. (Currently amended) A pharmaceutical composition comprising a therapeutically effective and TNF-α release-inhibiting amount of a compound according to claim 3, or a pharmaceutically-acceptable salt thereof, ~~for the treatment of an inflammatory condition comprising an autoimmune component,~~ in association with a pharmaceutically-acceptable diluent or carrier.

14. (Currently amended) A method for the treatment of conditions mediated by TNFα ~~that are inflammatory conditions comprising an autoimmune component~~ selected from rheumatoid arthritis, arthritis chronica progrediente, arthritis deformans, hemolytic anaemia, aplastic anaemia, pure red cell anaemia, idiopathic thrombocytopenia, systemic lupus erythematosus, polychondritis, scleroderma, Wegener granulomatosis, dermatomyositis, chronic active hepatitis, myasthenia gravis, psoriasis, Steven-Johnson syndrome, idiopathic sprue, ulcerative colitis, Crohn's disease, endocrine ophthalmopathy, Graves disease, sarcoidosis, multiple sclerosis, primary biliary cirrhosis, diabetes mellitus type I, uveitis, keratoconjuctivitis sicca, vernal keratoconjunctivitis, interstitial lung fibrosis, psoriatic arthritis, glomerulonephritis, asthma, bronchitis, pneumoconiosis, pulmonary emphysema, septic shock, meningitis, pneumonia, severe burns, and AIDS-related chachexia, which method comprises administering to a patient in need of such treatment a therapeutically-effective and TNFα-inhibiting amount of a compound according to claim 3, or a pharmaceutically-acceptable salt thereof.

15. (Currently amended) A pharmaceutical composition comprising a therapeutically effective and TNF-α release-inhibiting amount of a compound according to claim 12, or a pharmaceutically-acceptable salt thereof, ~~for the treatment of an inflammatory condition comprising an autoimmune component,~~ in association with a pharmaceutically-acceptable diluent or carrier.

16. (Currently amended) A method for the treatment of conditions mediated by TNFα ~~that is an inflammatory conditions comprising an autoimmune component~~ selected from rheumatoid arthritis, arthritis chronica progrediente, arthritis deformans, hemolytic anaemia, aplastic anaemia, pure red cell anaemia, idiopathic thrombocytopenia, systemic lupus erythematosus, polychondritis, scleroderma, Wegener granulomatosis, dermatomyositis, chronic active hepatitis, myasthenia gravis, psoriasis, Steven-Johnson syndrome, idiopathic sprue, ulcerative colitis, Crohn's disease, endocrine ophthalmopathy, Graves disease, sarcoidosis, multiple sclerosis, primary biliary cirrhosis, diabetes mellitus type I, uveitis, keratoconjuctivitis sicca, vernal keratoconjunctivitis, interstitial lung fibrosis, psoriatic arthritis, glomerulonephritis, asthma, bronchitis, pneumoconiosis, pulmonary emphysema, septic shock, meningitis, pneumonia, severe burns, and AIDS-related chachexia, which method comprises administering to a patient in need of such treatment a therapeutically-effective and TNFα-inhibiting amount of a compound according to claim 12, or a pharmaceutically-acceptable salt thereof.